Message

From: Pfennercrisp **Personal Email / Ex. 6**
Sent: 7/22/2014 5:23:50 PM
To: Olden, Kenneth [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8979224c77ea4d559f70cab1688f28aa-Olden, Kenneth]
CC: Cogliano, Vincent [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=51f2736376ac4d32bad2fe7cfef2886b-Cogliano, Vincent]; Kavlock, Robert [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=eebac67f01094409a7fdaa955a837884-Kavlock, Robert]
Subject: Restoring IRIS's Credibility
Attachments: The_Assessment_of_the_Validity_and_Currency_of_EPA..pdf; Appendix_B-IRIS_Pesticides_(2-1-2014)v2.pdf

Dr. Kenneth Olden
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Dear Dr. Olden:

This correspondence serves as a follow-up to the very brief conversation we had after the conclusion of the symposium on the IRIS program presented at the Society for Risk Analysis meeting in Baltimore last December. As we were leaving the session, I asked you what your plans were for dealing with the extensive number of pesticides for which guidance values reside on the IRIS database but for which NCEA no longer has responsibility for maintaining and assuring their accuracy and currency. Unfortunately, we did not have the opportunity to discuss this topic in depth, but I did get the impression that it was an issue with which you may have had little familiarity. In my view, it is a big problem for IRIS and NCEA and a significant impediment to the reestablishment of IRIS as a credible repository of Agency-generated human health guidance. It is a distraction and a negative influence on your efforts to respond constructively to the recommendations made by the NRC in the formaldehyde report and its follow-up comments and recommendations in its more recent report on IRIS.

Perhaps, some historical perspective on the concept and implementation of IRIS may be of value. Back in the late 70's and early 80's, the then-Office of Drinking Water (ODW) was being bombarded with requests to provide non-regulatory health-based guidance to drinking water systems and communities with residents on individual wells for chemicals for which no MCLs had been promulgated. In addition, the U.S. Geological Survey had recently issued the results of a survey which monitored pesticides in groundwater, particularly that which served as drinking water sources. Thus, the Health Advisory Program was created. At the same time, another part of the Office of Water was developing Ambient Water Quality Criteria under the Clean Water Act. And, of course, the Office of Pesticide Programs (OPP) was managing its registration program.

It was clear that some kind of consensus process needed to be established so that all of the program offices in the Agency would be speaking with one voice on a specific chemical as they carried out their respective regulatory responsibilities. In addition, there needed to be a single database created in which the guidance could be stored; that was IRIS. Thus, the experiment was begun in about 1982-1983, using pesticide chemicals as the first case studies. The reason is obvious. A standard, relevant and useful body of data existed for every food-use pesticide, as required under 40 CFR Part 158, in the registration process, a luxury not afforded to chemicals in other categories. OHEA (now, NCEA)-Cincinnati took the lead on assembling and housing the materials needed for the consensus group to use for "number-crunching." Michael Dourson had the lead for this task. He, along with Reto Engler from OPP (now, deceased) and myself, as the representative from ODW, then began about three years of meetings in which we alone derived RfDs for pesticides. As our effort gained traction, it was deemed appropriate to expand participation in this exercise to other Agency programs. Thus, the Reference Dose Work Group was formed in 1985, initially made up only of Headquarters and NCEA staff, later expanded to include Regional staff. A relatively short-lived Carcinogen Risk Assessment Verification Endeavor Work Group (CRAVE) (chaired by Dr. Rita Schoeny) was established some years later, but never was afforded the time to make many cancer calls for the pesticides for which RfDs had been derived. Beginning in 1995, NCEA revised its operational procedures by which IRIS assessments were developed and updated. The two work groups were disbanded, document development became the sole responsibility of NCEA, with members of the two work groups (or their replacements) now serving only as internal peer reviewers.

Another very significant change occurred at the 1995 time point, which is not widely remembered and rarely acknowledged. The NCEA-led Agency consensus activities on pesticides ended. The responsibility for the development of health-based values reverted to the Office of Pesticide Programs (OPP). Maintenance and updating of IRIS values by NCEA for pesticides ceased, with

minor exceptions. If the substance is used primarily for purposes other than as a pesticide, NCEA has retained the responsibility for updating the assessment. In these instances, OPP is consulted and the outcome of the assessment generally represents a consensus opinion.

So, what does this say about the credibility of the IRIS entries for pesticides? Most of the IRIS entries uploaded between 1987 and 1989 were derived by Drs. Dourson, Engler and myself, later verified by the RfD Workgroup. That means these values are ~30 years old—and way out of date. As I have shown in my paper attached to this email, nearly 200 of the 557 entries on IRIS are currently-registered or recently-cancelled pesticides. Those substances that I have defined as "recently-cancelled" have had changes made to their RfDs and/or cancer calls by the Office of Pesticide Programs AFTER their last significant revision on IRIS. Of the nearly 200 chemicals, almost 90% of the IRIS entries for these substances are incorrect, either for the RfD or the cancer call or both. This is the 800-pound elephant in the room. This problem needs to be corrected, swiftly and thoroughly, if there is any hope for restoring credibility to IRIS.

I prepared the attached paper entitled *The Assessment of the Validity and Currency of EPA's Integrated Risk Information System (IRIS) Database Entries for Pesticides* on my own, at the request of no one. I conducted this analysis because I have been troubled for many years by IRIS's continued misrepresentation of the official Agency positions on pesticides. This constitutes a disservice to Agency staff and programs and outside parties in the risk assessment community who are obligated by policy (e.g., the Superfund program and Regions) or resort, for lack of their own independent resources, to the use of IRIS values in their risk assessments. The paper contains a chemical-by-chemical analysis of all 557 IRIS substances, along with a set of recommendations for remedying the situation. Responsibility for implementation of the remedies lies not only with NCEA, but also with OPP and OW. The remedies are simple, easy to implement and will require minimal resource allocation. Some of the groundwork has already been done by virtue of the conduct of this analysis. I will be sharing my analysis with OPP and OW's Office of Science and Technology as well, since they each have a role, along with NCEA, in bringing the situation up-to-date.

If you have any questions or comments, please do not hesitate to contact me. I look forward to hearing from you.

Sincerely,

Penelope A. Fenner-Crisp, Ph.D., DABT
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